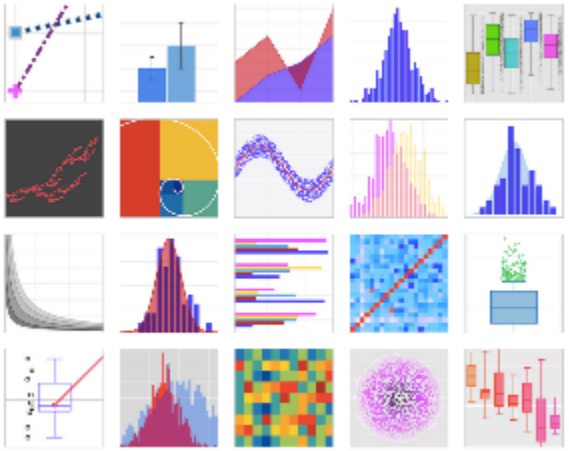

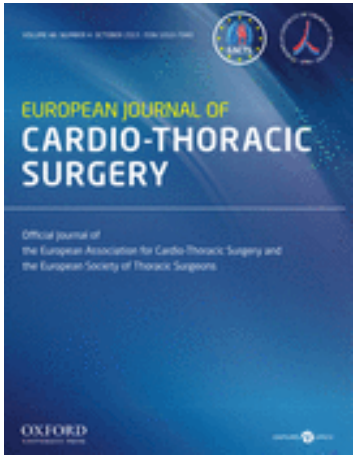

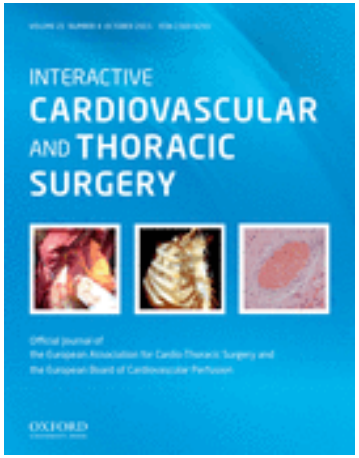

STATISTICAL DATA AND REPORTING GUIDELINES: IMPORTANT TO GET YOUR PAPER PUBLISHED

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CONFLICT OF INTEREST

None to declare

GUIDELINES

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GUIDELINE

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Statistical and data reporting guidelines for the *European Journal of Cardio-Thoracic Surgery* and the *Interactive CardioVascular and Thoracic Surgery*

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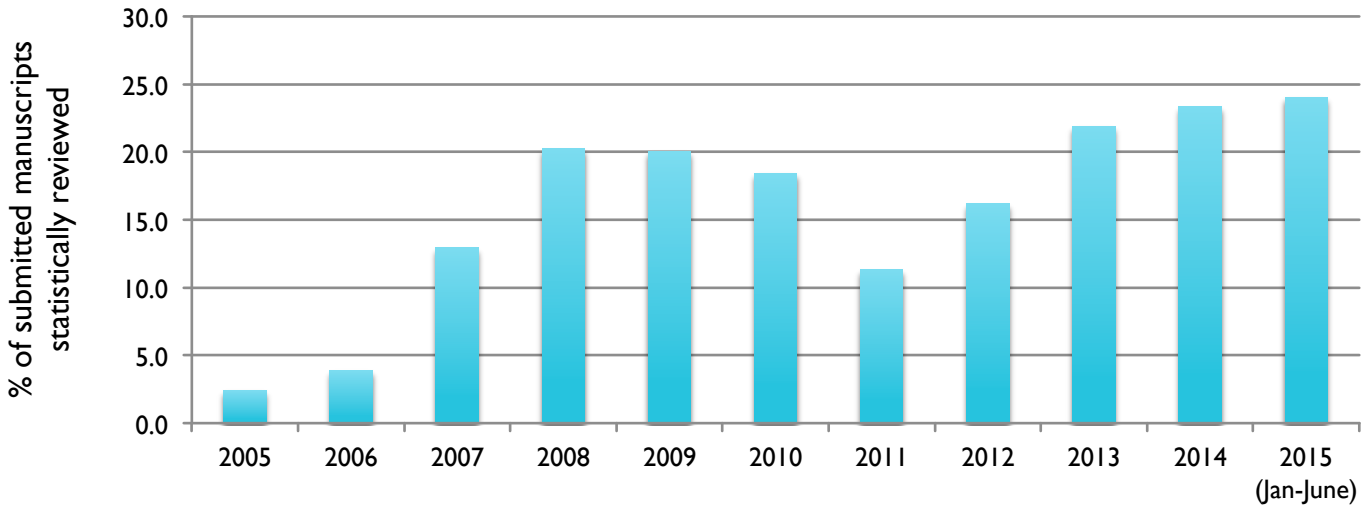
SUMMARY

- Existing recommended guidelines [1] for data reporting were published in 1988!
-



Approximately 1 in 4 manuscripts submitted to EJCTS are referred for statistical review

- Currently 5 statistical consultants on the editorial board
- Guidelines developed based on experience of all consultants to make clear expectations to those submitting research, and highlight common errors

[1] Guidelines for data reporting and nomenclature for The Annals of Thoracic Surgery. Ann Thorac Surg 1988;46:260–1.

STATISTICAL REVIEW PROCESS

Areas considered:

1. Was there a clear study design and the objectives well formulated?
2. Were the statistical analysis methods clearly described?
3. Were the statistical methods appropriate for the study/data?
4. Were the data appropriately summarized?
5. Were the statistical results adequately reported and inferences justified?

1. EXISTING REPORTING GUIDELINES

TRIPOD

PRISMA

TRANSPARENT REPORTING of SYSTEMATIC REVIEWS and META-ANALYSES

CONSORT

STROBE Statement

Strengthening the reporting of observational studies in epidemiology

EJCTS Guidelines **supplement** existing reporting statements—not replace them!

1. STUDY DESIGN: CORE REQUIREMENTS

- Objective / hypothesis and type of study
- Data acquisition methods (incl. post-discharge follow-up)
- Inclusion and exclusion criteria
- Sample size rationale – calculations should be reproducible
- Randomization and blinding (if relevant)
- Potential sources of bias → statistical adjustment methods used

1. STUDY DESIGN: DEFINITIONS

- Explicitly define outcomes, e.g.
  - '(Peri-)operative mortality' – in-hospital or 30-day?
  - Time origin for time-to-event variables – surgery, randomisation, discharge, etc.?
  - All-cause or cause-specific mortality?
- Use accepted definitions where available
  - E.g. valve [1] & TAVI [2]
- Avoid ambiguous or undefined study variables
  - E.g. 'normal' vs. 'abnormal' white cell count

[1] Akins CW, et al. Guidelines for reporting mortality and morbidity after cardiac valve interventions. Eur J Cardiothorac Surg 2008;33: 523–8.
[2] Kappetein AP, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document (VARC-2). Eur J Cardiothorac Surg 2012;42:S45–60.

2. DESCRIPTION OF STATISTICAL ANALYSIS

- A description of statistical methods used, and when they were used
- Additional information request for advanced statistical methods
- Handling of missing data
- Phrasing and terminology, e.g. incidence *vs.* prevalence or multivariate *vs.* multivariable

2. DESCRIPTION OF STATISTICAL ANALYSIS: REGRESSION MODELS

- Inclusion of adjustment covariates
  - Univariable screening
  - Stepwise regression methods (details of algorithm required)
  - Covariates forced into model
  - All covariates included
  - Consideration to over-fitting and stability?
- Functional form of continuous covariates (e.g. transformations, dichotomization)

2. DESCRIPTION OF STATISTICAL ANALYSIS: PROPENSITY SCORE MATCHING

Limited guidance, but recommendations in literature [1] include:

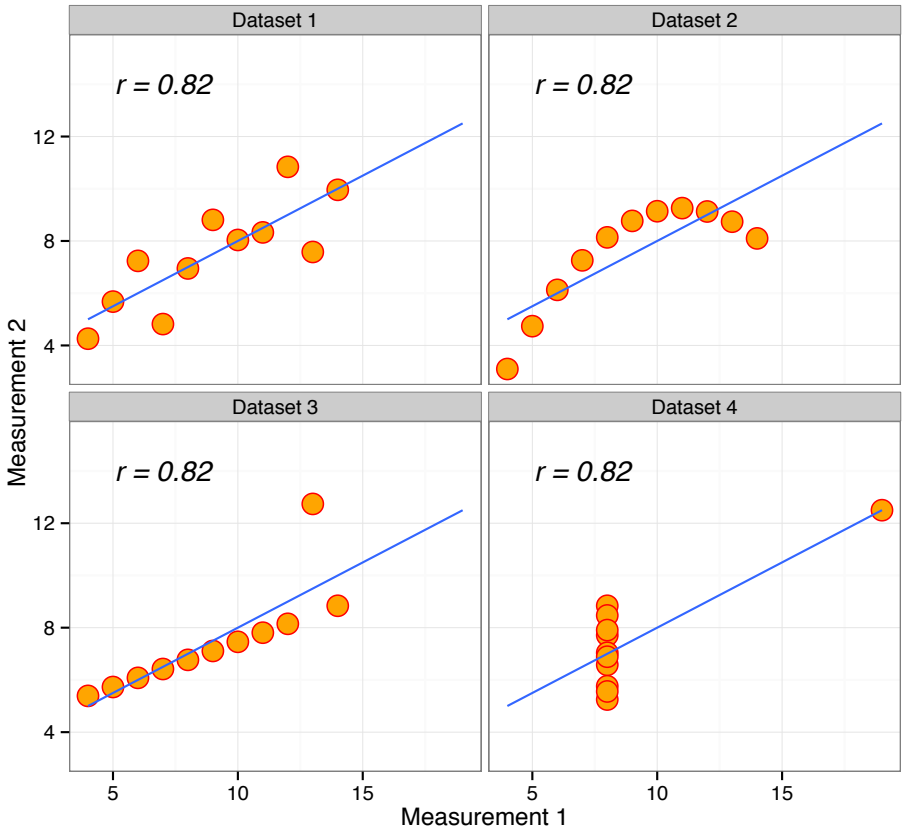
- Evaluate balance between baseline variables using standardised difference, not just hypothesis tests
- Provide details of matching algorithms used (incl. caliper details, match ratio, with/without replacement) – not just software!
- Lack of balance requires further iterations of propensity score model building (e.g. interaction terms) – don't stop at first attempt!
- Describe statistical methodology used to estimate treatment effects in the matched data

[1] Austin, P. C. (2007). Propensity-score matching in the cardiovascular surgery literature from 2004 to 2006: a systematic review and suggestions for improvement. The Journal of Thoracic and Cardiovascular Surgery, 134(5), 1128–35.

3. APPROPRIATE METHODS

- Regression models should have assumptions checked, and if necessary be assessed using suitable diagnostics and goodness-of-fit tests
  - E.g. Proportional hazards assumption for Cox regression models
- Correct statistical model / methodology for data
  - E.g. using logistic regression when a Cox model should have been used
  - E.g. independent samples test for paired data
- Multivariable models should have an adequate event-per-variable ratio
  - E.g. fitting a logistic regression model with 7 covariates to data with 20 events and 1000 subjects using maximum likelihood would be inappropriate

3. PRESENTING DATA GRAPHICALLY



Anscombe's quartet *

- Same number of points
- Same Pearson sample correlation coefficient
- Same linear regression line fit
- Same marginal means and standard deviations

Present appropriate plots of your data when possible

* Anscombe FJ. Graphs in statistical analysis. Am Stat 1973;27:17–21.

4. DATA REPORTING

- Include summary table of patient/surgical characteristics, stratified by treatment groups if a comparison study
- Location statistics (e.g. mean, median) should always be reported with appropriate measure of variability (e.g. median, IQR)
- Always report what summary statistics are reported
  - "average age was 65 years (41-79) years" – is it mean and range, median and (1^{st}, 3^{rd}) quartiles?

4. DATA REPORTING: AVOIDABLE ISSUES

Table 1. Patient and operative characteristics data by CPB technique with statistical comparison.

	Overall		On-pump		Off-pump		(%)	*P*
Total number	*n*=3402		*n*=1173		*n*=2229			
Logistic EuroSCORE (%)	2.4 ± 2.5		2.4 ± 2.8		2.3 ± 2.3		1.8	0.965
Age (years)	61.7 ±10.6		61.1 ± 10.3		61.9 ± 10.7		-8.1	0.026
BMI (kg/m^2)	28.5 ± 4.6		28.7 ± 4.7		28.4 ± 4.5		6.1	0.090
	N	**%**	***N***	**%**	***N***	**%**		
Female	880	25.9%	325	27.7%	555	24.9%	6.4	0.083
Preoperative AF	69	2.0%	28	2.4%	41	1.8%	3.8	0.343
Urgent	733	21.5%	271	23.1%	462	20.7%	5.7	0.119
NYHA III/IV	645	19.0%	225	19.2%	420	18.8%	0.9	0.846
History of neurological dysfunction	53	1.6%	25	2.1%	28	1.3%	6.8	0.070

Columns labeled

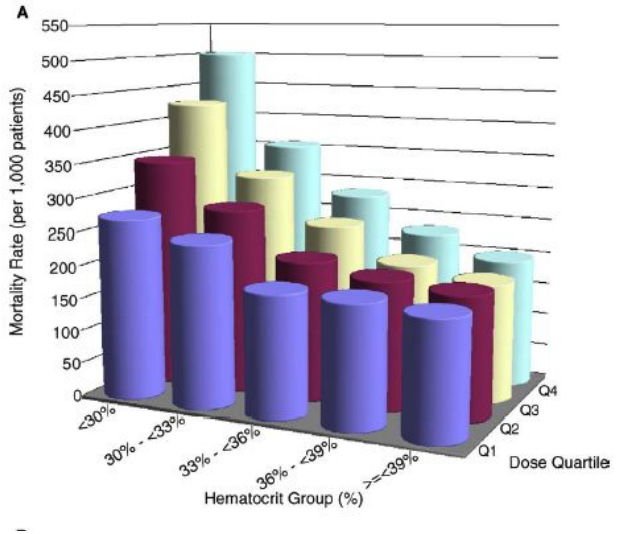
Appropriate and consistent precision

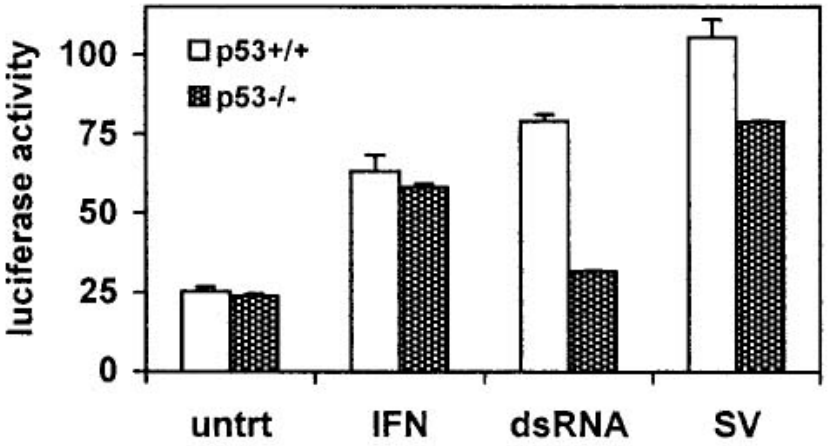
Units included

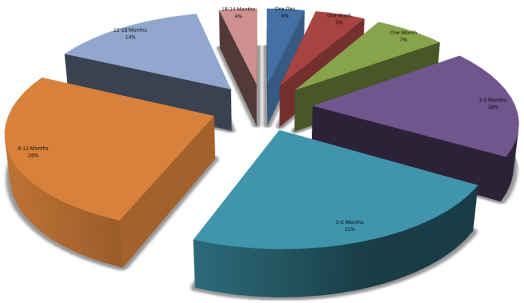
Number of subjects add up correctly

Percentages correctly rounded

4. DATA REPORTING: CHARTS







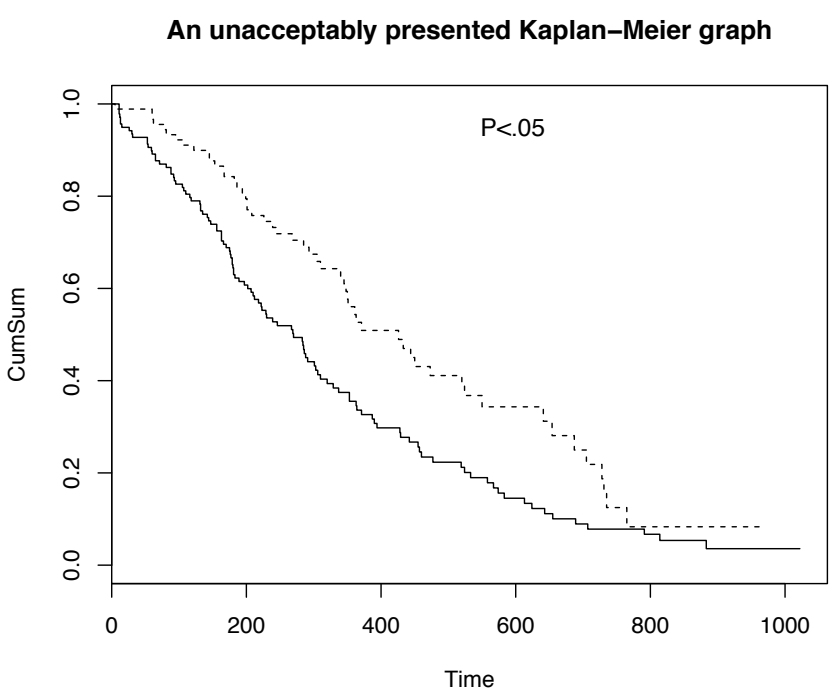
- Statistical figures are for summarizing complex data
- Readers will be drawn to them, so make them intuitive, sensible and clear

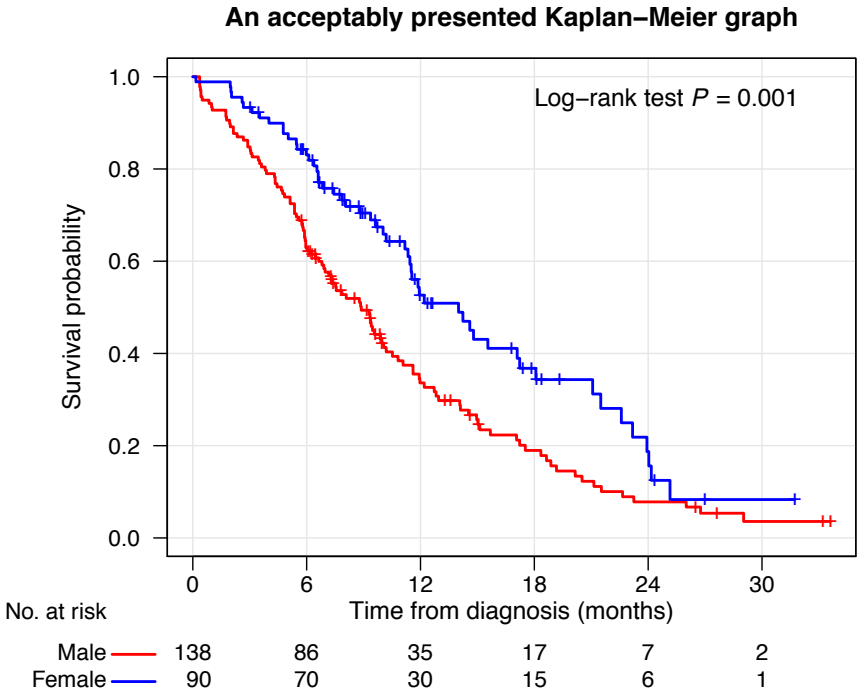
Wainer H (1984) How to display data badly. The American Statistician 38:137-147.
https://www.biostat.wisc.edu/~kbroman/topten_worstgraphs/

5. RESULTS

- *P*-values alone ≠ results → effect sizes and confidence intervals
- Full regression models should be reported – not just significant terms
- Details of any deviations from the planned study
- *P*-values and statistics reported to appropriate precision

5. RESULTS: PRESENTING PLOTS





5. DISCUSSION & CONCLUSIONS

- Association ≠ causation
- *P*-values ≠ probability null hypothesis is true
- Absence of evidence ≠ evidence of absence, e.g. *P*=0.60 only tells us there is insufficient evidence for an effect, which might be due to:
  - No effect being present
  - Large variability
  - Insufficient information in the data due to small sample size
- Statistical significance ≠ clinical significance
- Study weaknesses should go beyond commenting on the sample size and observational data

CONCLUSIONS

- EJCTS & ICVTS Statistical and Data Reporting Guidelines inform authors on what statistical reviewers are looking for
- A well analyzed study allows reviewers to focus on what is important—the science!
- It is advised that a biostatistician be involved in the analysis
- Correct and well-reported (and correct) statistical analysis essential to getting your paper published!

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